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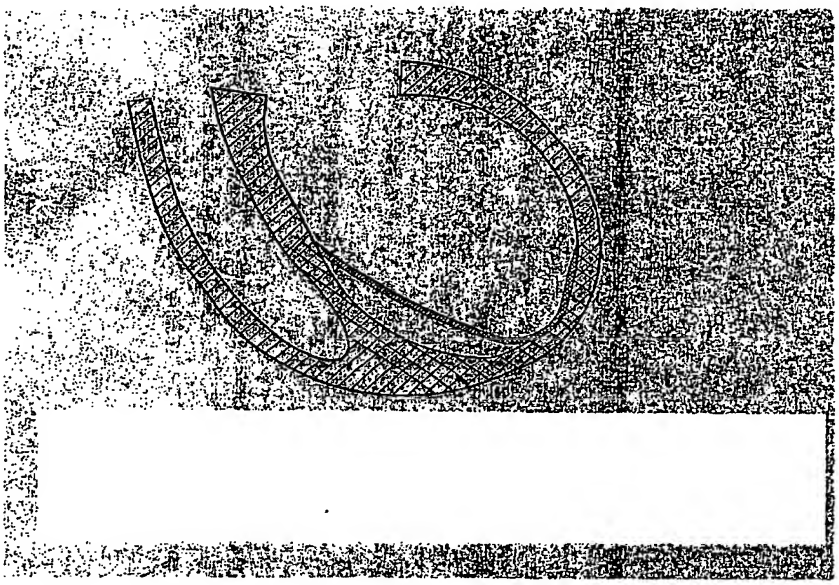
(54) **Title:** AN APICAL PATCH AND METHOD OF USE



(57) **Abstract:** An apparatus, such as a patch, may be used as part of a ventricular repair system in performing surgical ventricular restoration. The patch may allow a surgeon to reconstruct a ventricle into an appropriate shape while excluding a majority, if not all, of any akinetic tissue. The ventricle may be a left ventricle of a human heart. The patch may be formed in substantially the same shape as the appropriate shape which a surgeon desires to reshape the ventricle. The patch may be formed of a variety of biocompatible materials. The patch may be formed from and/or include materials that flex/contract in response to stimuli.

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

TITLE: AN APICAL PATCH AND METHOD OF USE

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates generally to surgical methods and apparatus for performing surgical ventricular repair. A specific embodiment of the invention relates to methods and apparatus for repairing a dilated left ventricle of a human heart.

2. Description of the Related Art

The function of a heart in an animal is primarily to deliver life-supporting oxygenated blood to tissue throughout the body. This function is accomplished in four stages, each relating to a particular chamber of the heart. Initially deoxygenated blood is received in the right auricle of the heart. This deoxygenated blood is pumped by the right ventricle of the heart to the lungs where the blood is oxygenated. The oxygenated blood is initially received in the left auricle of the heart and ultimately pumped by the left ventricle of the heart throughout the body. It can be seen that the left ventricular chamber of the heart is of particular importance in this process as it is relied upon to pump the oxygenated blood initially through an aortic valve into and ultimately throughout the entire vascular system.

The shape and volume of the normal heart are of particular interest as they combine to dramatically affect the way that the blood is pumped. The left ventricle which is the primary pumping chamber, is somewhat elliptical, conical or apical in shape in that it is longer, long axis longest portion from aortic valve to apex, than it is wide, short axis widest portion from ventricle wall to septum, and descends from a base with a decreasing cross-sectional circumference, to a point or apex. The left ventricle is further defined by a lateral ventricle wall and a septum, which extends between the auricles and the ventricles.

Two types of motion accomplish the pumping of the blood from the left ventricle. One of these motions is a simple squeezing motion, which occurs between the lateral wall and the septum. The squeezing motion occurs as a result of a thickening of the muscle fibers in the myocardium. This compresses the blood in the ventricle chamber and ejects it into the body. The thickening changes between diastole and systole. This is seen easily by echocardiogram, PET and MRI imaging and can be routinely measured.

The other type of motion is a twisting or writhing motion, which begins at the apex and rises toward the base. The rising writhing motion occurs because the heart muscle fibers run in a circular or spiral direction around the heart. When these fibers constrict they cause the heart to twist initially at the small area of the apex, but progressively and ultimately to the wide area of the base. These squeezing and twisting motions are equally important, as they are each responsible for moving approximately one-half of the blood pumped. The contractility or stiffness of these fibers are major determinants in how well the ventricle pumps.

The amount of blood pumped from the left ventricle divided by the amount of blood available to be pumped is referred to as the ejection fraction of the heart. Generally, a healthier heart has a higher ejection fraction. A normal heart, for example may have a total volume of one hundred milliliters and an ejection fraction of sixty percent. Under these circumstances, 60 milliliters of blood are pumped with each beat of the heart. It is this volume in the normal heart of this example that is pumped with each beat to provide nutrients including oxygen to the muscles and other tissues of the body.

Realizing that the heart is part of the body tissue, and the heart muscle also requires oxygenated blood, it can be appreciated that the normal function of the heart is greatly upset by clotting or closure of the coronary arteries. When the coronary arteries are blocked, an associate portion of the heart muscle becomes oxygen-starved and begins to die. This is clinically referred to as a heart attack. Ischemic cardiomyopathy typically occurs as the rest of the heart dilates in an attempt to maintain the heart's output to the body.

As the ischemia progresses through its various stages, the affected myocardium dies losing its ability to contribute to the pumping action of the heart. The ischemic muscle is no longer capable of contracting so it cannot contribute to either squeezing or twisting motion required to pump blood. This non-contracting tissue is said to be akinetic. In severe cases the akinetic tissue, which is not capable of contracting, is in fact elastic so that blood pressure tends to develop a bulge or expansion of the chamber. This muscle tissue is not only akinetic, in that it does not contribute to the pumping function, but it is in fact dyskinetic, in that it detracts from the pumping function. This is particularly detrimental as the limited pumping action available, as the heart loses even more of its energy to pumping the bulge instead of the blood.

The body seems to realize that with a reduced pumping capacity, the ejection fraction of the heart is automatically reduced. For example, the ejection fraction may drop from a normal sixty percent to perhaps twenty percent. Realizing that the body still requires the same volume of blood for oxygen and nutrition, the body causes its heart to dilate or enlarge in size so that the smaller ejection fraction pumps about the same amount of blood. As noted, a normal heart with a blood capacity of seventy milliliters and an ejection fraction of sixty percent would pump approximately 42 milliliters per beat. The body seems to appreciate that this same volume per beat can be maintained by an ejection fraction of only thirty-percent if the ventricle enlarges to a capacity of 140 milliliters. This increase in volume, commonly referred to as "remodeling", not only changes the volume of the left ventricle, but also its shape. The heart becomes greatly enlarged and the left ventricle becomes more spherical in shape losing its apex. Such a situation is illustrated in FIG. 1, which shows a cross sectional view of an enlarged human heart.

On the level of the muscle fibers, it has been noted that dilation of the heart causes the fibers to reorient themselves so that they are directed away from the inner heart chamber containing the blood. As a consequence, the fibers are poorly oriented to accomplish even the squeezing action, as the lines of force become less perpendicular to the heart wall. This change in fiber orientation occurs as the heart dilates and moves from its normal elliptical shape to its dilated spherical shape. The spherical shape further reduces pumping efficiency since the fibers which normally encircle the apex facilitate writhing are changed to a more flattened formation as a result of these spherical configurations.

Of course, this change in architecture has a dramatic effect on wall thickness, radius, and stress on the heart wall. In particular, it will be noted that absent the normal conical shape, the twisting motion at the apex, which can account for as much as one half of the pumping action, is lost. As a consequence, the more spherical architecture must rely almost totally on the lateral squeezing action to pump blood. This lateral squeezing action is inefficient and very different from the more efficient twisting action of the heart.

Although the dilated heart may be capable of sustaining life, it is significantly stressed and rapidly approaches a stage where it can no longer pump blood effectively. In this stage, commonly referred to as congestive heart failure, the heart becomes distended and is generally incapable of pumping blood returning from the lungs. This further results in lung congestion and fatigue. Congestive heart failure is a major cause of death and disability in the United States where approximately 400,000 cases occur annually.

Following coronary occlusion, successful acute reperfusion by thrombosis, (clot dissolution) percutaneous angioplasty, or urgent surgery can decrease early mortality by reducing arrhythmias and cardiogenic shock. It is also known that addressing ischemic cardiomyopathy in the acute phase, for example with reperfusion, may salvage the epicardial surface. Although the myocardium may be rendered akinetic, at least it is not dyskinetic. Post-infarction surgical re-vascularization can be directed at remote viable muscle to reduce ischemia. However, it does not address the anatomical consequences of the akinetic region of the heart that is scarred. Despite these techniques for monitoring ischemia, cardiac dilation and subsequent heart failure continue to occur in approximately fifty percent of post-infraction patients discharged from the hospital.

The majority of blockages of the arteries are generally on the Left Anterior Descending (LAD) artery. This artery feeds the anterior portion of the heart and the apex. A blockage in this artery will lead to an infarction that includes an anterior portion of the heart along with the apex. The structure of the apex involves all walls of the ventricle, so that if the apex becomes akinetic it involves all the walls that make up the apex. The extent of each wall's involvement will differ, but the involvement will be in three dimensions and not limited to one wall of the ventricle.

Various surgical approaches have been taken to repair the dilation that occurs after the apex and anterior wall of the left ventricle have had an infarction. These approaches are primarily intended to reduce the ventricular volume, while making an attempt to restore ventricular shape. Some of these procedures involve removing dyskinetic and akinetic regions of the heart, then surgically joining the viable portions of the myocardial walls, typically with the use of a patch surgically placed in the walls using a Fontan stitch. The Fontan stitch is a stitch placed on the border zone between akinetic and viable muscle, when tightened this stitch form a rim onto which the patch can be sewn.

Other techniques have used the patch to cover or exclude the akinetic or dyskinetic portions of the ventricle. The patches that are used are constructed from flat, generally rectangular sheets of material. The correctly shaped patch to exclude tissue or cover a hole is cut from these rectangular sheets and sutured into place. Since the patch is flat, it tends to make the ventricle more spherical. This situation is illustrated in FIG. 2, which shows a cross-sectional view of human heart with a flat patch 200.

These surgical procedures have met with some success as the ejection fraction has been increased, for example, from twenty-four percent to forty-two percent. These procedures also have shown that even the most experienced surgeons can incorrectly repair a dilated ventricle. Recent studies have shown that the most experienced surgeon in this procedure has induced mitral regurgitation in 33% of one patient group that didn't have mitral regurgitation prior to surgery, due their ventricles being too spherical after surgery. Some patients whose ventricles are made too small are even worse off after surgery than before surgery. The difficulty of reconstructing a dilated ventricle has kept the procedure restricted to a very small group of surgeons who are very experienced in the procedure.

One difficulty in reconstructing the left ventricle is that the ventricle is three-dimensional and it is being repaired with a flat or two dimensional patch. The apex of the left ventricle has a very small radius, so that when it's tissue dies due to infarction the dead tissue is present on all sides of the heart along with another portion of dead tissue on the anterior side. To address this three dimensional issue surgeons can either exclude all the tissue of the apex by placing their patch at an angle almost parallel to the mitral valve. This excludes the akinetic tissue, but results in making the ventricle spherical, potentially leading to mitral regurgitation and reducing ventricle efficiency, as illustrated in FIG. 2. This method of repairing the ventricle also eliminates the apex, which is a key component in the twisting and contracting of the ventricle. This method may also make the ventricle too small as the cavity is greatly reduced to exclude all the akinetic tissue.

What is needed, therefore, is a reliable method and apparatus to allow a surgeon to perform surgical ventricular restoration without having to compromise on the shape of the ventricle to exclude all akinetic tissue or to compromise on excluding all akinetic tissue to create the proper shape.

SUMMARY

In response to the problems mentioned above, there is disclosed an embodiment of an improved endoventricular patch to be used in ventricular repair. In an embodiment, a patch may be used to repair a left ventricle of a human heart. The patch may have a predetermined shape. The patch has a shape that is substantially the same as the shape of a portion of the left ventricle. In other words, the patch has a conical shape with a round apex. When inserted into a patient, the tip of the cone may act as an apex of the heart. The patch may assist in reforming or reconstructing a ventricle. The patch may assist in reforming a contour of a ventricle. The product may be made from a bio-prosthetic like a porcine or bovine pericardium, or a prosthetic material like polyester or PTFE. Such a product may be fabricated by weaving or knitting or by using one or more continuous sheets. Optionally, the patch could have radiopaque markings. Furthermore, the patch could be made of ion exchange material, which can act as an artificial muscle.

The procedure addresses the ability of the surgeon to perform a surgical ventricular repair procedure that allows the surgeon to ensure that he gets the intended size and shape of the ventricle with an apex while at the same time excluding all the akinetic and dyskinetic tissue.

The procedure, by excluding much, if not all, of the akinetic and dyskinetic tissue while allowing the surgeon to create the proper shape with an apex, significantly reduces stress on the heart muscle and improves surgical outcome. The procedure, by being done with a precise device allows the surgeon to make the procedure repeatable and reliable. The device takes the variation out of the procedure.

BRIEF DESCRIPTION OF THE DRAWINGS

The above brief description as well as further objects, features and advantages of the methods and apparatus of the present invention will be more fully appreciated by reference to the following detailed description of presently preferred but nonetheless illustrative embodiments in accordance with the present invention when taken in conjunction with the accompanying drawings in which:

FIG. 1 An embodiment of a sectional view of dilated heart.

FIG. 2 An embodiment of a sectional view of a dilated heart with a flat patch.

FIG. 3 An embodiment of an apical patch.

FIG. 4 An embodiment of an apical patch cut to be placed in a patient.

FIG. 5 An embodiment of a sectional view of dilated heart with an apical patch.

While the invention is susceptible to various modifications and alternative forms, specific embodiments thereof are shown by way of example in the drawings and may herein be described in detail. The drawings may not be to scale. It should be understood, however, that the drawings and detailed description thereto are not intended to limit the invention to the particular form disclosed, but on the contrary, the intention is to cover all modifications, equivalents and alternatives falling within the spirit and scope of the present invention as defined by the appended claims.

DETAILED DESCRIPTION

Turning now to FIG. 3, there is one embodiment of apical patch 300 which may be "cone shaped" similar to the lower portion of the left ventricle. This conical shape may be open at base 302 of the patch and have tip 304, which may function as a new apex after insertion into the patient.

In one embodiment, three-dimensional patch 300 may be made out of a single piece of material to make the patch seamless. Patch 300 may come in different sizes; sizes may correspond to a size of a shaping device or to the size of an appropriate ventricle. Patch 300 may be easily cut, so that surgeons can match the material to the akinetic area of the patients heart. Such a modified patch is illustrated in FIG. 4.

Patch 300 may be made from a polyester, for example a Dacron™ like material. Such material is currently used for implantable prosthetics. Woven materials, such as polyesters, may be impregnated with materials which function to inhibit penetration of fluids such as blood. Materials which may be impregnated to inhibit leaking may include collagen. Patch 300 can be manufactured in a variety of methods known in textile manufacturing (e.g., bonding, weaving, cut to shape and sewing etc.). An embodiment may have the three dimensional patch made from ePTFE (expanded polytetrafluoroethylene). In some embodiments, patch 300 may be formed from bioprosthetic Additionally it can be made out of bioprosthetic materials. Examples of bioprosthetic materials may include, but are not limited to, porcine cells and bovine cells.

In an embodiment apical patch 300 may be made of synthetic material that when subjected to a stimulus flexes or contracts. Synthetic material which flexes/contracts in response to stimuli may aid in contraction of the left ventricle. In this embodiment, patch 300 may be made out of ion exchange material. Ion exchange material may be coated with a noble metal, shape memory metals, and/or electrosensitive gels that deform in reaction to an electrical signal. Such a patch could be simulated to flex in synchronization with the cardiac cycle of a pacemaker or other implantable controller. A controller may be programmed transcutaneously and the amount of contraction may be controlled and adjusted. An energy source of the electric signal may come from a rechargeable battery that can be charged transcutaneously.

An embodiment may have apical patch 300 made totally from biologic material that contracts and assists in the contraction of the ventricle. Such an embodiment may be made from autologous cells, xeno transplant, cultured skeletal muscle cells, cultured bone marrow cells, cultured cardiac muscle cells, and/or cultured smooth muscle cells. A growth factor to stimulate tissue growth may be impregnated in the biologic material to be released over time.

Patch 300 may also be a structure that is impregnated with biological material that contracts and assists in the contraction of the ventricle. The structure could be impregnated with skeletal muscle cells, bone marrow cells, cardiac muscle cells, and/or smooth muscle cells. The structure may be bioabsorable and may be absorbed by the body over time, leaving only the biological material. In an embodiment, a growth factor may be impregnated in the structure to be released over time.

In an embodiment, three-dimensional patch 300 may have radiopaque markings in a predetermined pattern. Radiopaque markings may allow doctors to monitor the patch and its interaction with the surrounding tissue after insertion into the patient.

In an operation, a surgeon determines what size, shape and orientation he intends to reconstruct a ventricle (the "intended" or appropriate shape). During a surgical procedure, the surgeon then opens the ventricle and notes the extent of the scar inside the ventricle. Patch 300 may be placed in the ventricle. A surgeon may mark the extent of the scar tissue on patch 300. Patch 300 may be removed. Upon removal excess material may be trimmed from patch 300. Patch 300 is placed back in the ventricle and the surgeon ensures that the apex of the patch is located at the apex of the ventricle. Patch 300 may be sutured into the ventricle, excluding much, if not all, of the akinetic

tissue and creating a new apex. In some embodiments it may be possible and/or desirable to exclude all of the akinetic tissue.

In an embodiment of the procedure, a surgeon may decide on the volume of the ventricle. The surgeon may use a shaping device and a matching apical patch. After the ventricle is open, a Fontan stitch can placed on the border zone of the akinetic and viable tissue. The shaping device is introduced into the ventricle and the Fontan stitch is pulled tight. A portion of the shaping device projects out of the Fontan stitch. Apical patch 300 may be cut such that the shape of the patch matches the projection of the shaping device outside of the Fontan stitch. Cut patch 300 may be sewn to a portion of the heart hemostatically. The shaping device is removed prior to completely sewing patch 300. Such a procedure would yield a reconstructed ventricle of the size and shape that is substantially the same as the intended or appropriate shape.

Further modifications and alternative embodiments of various aspects of the invention will be apparent to those skilled in the art in view of this description. Accordingly, this description is to be construed as illustrative only and is for the purpose of teaching those skilled in the art the general manner of carrying out the invention. It is to be understood that the forms of the invention shown and described herein are to be taken as the presently preferred embodiments. Elements and materials may be substituted for those illustrated and described herein, parts and processes may be reversed, and certain features of the invention may be utilized independently, all as would be apparent to one skilled in the art after having the benefit of this description of the invention. Changes may be made in the elements described herein without departing from the spirit and scope of the invention as described in the following claims

WHAT IS CLAIMED IS:

1. A ventricular repair system, comprising:

a patch comprising a predetermined shape, wherein the predetermined shape is substantially nonplanar, and wherein the predetermined shape is substantially similar to a portion of an appropriate ventricle.

2. The ventricular repair system of claim 1, wherein the patch is configurable to alter at least a portion of a contour of a ventricle to a second contour of the ventricle substantially similar to the predetermined shape during use.

3. The ventricular repair system of claim 1, wherein the patch is substantially conical in shape.

4. The ventricular repair system of claim 1, wherein the patch further comprises a concave surface and a convex surface.

5. The ventricular repair system of claim 4, wherein the concave surface forms an interior surface of the ventricle during use.

6. The ventricular repair system of claim 1, wherein the patch is substantially conical in shape, wherein the patch further comprises a base and a tip

7. The ventricular repair system of claim 6, and wherein the base comprises an opening.

8. The ventricular repair system of claim 1, wherein the patch is substantially conical in shape, wherein the patch further comprises a base and a tip, wherein the base comprises an opening, and wherein the tip assists in defining an apex of a repaired ventricle.

9. The ventricular repair system of claim 1, wherein the patch is substantially conical in shape, wherein the patch further comprises a base and a tip, wherein the base comprises an opening, and wherein the tip assists in defining an apex of a repaired ventricle.

10. The ventricular repair system of claim 1, wherein the patch further comprises at least two curvatures.

11. The ventricular repair system of claim 1, wherein the ventricle comprises non-viable tissue, and wherein the patch is configurable to exclude at least a portion of the non-viable tissue.

12. The ventricular repair system of claim 1, wherein the ventricle comprises a left ventricle of a human heart.

13. The ventricular repair system of claim 1, wherein the patch further comprises a polyester.

14. The ventricular repair system of claim 1, wherein the patch further comprises ePTFE.

15. The ventricular repair system of claim 1, wherein the patch further comprises bioprosthetic materials.

16. The ventricular repair system of claim 1, wherein the patch further comprises a material configurable to substantially deform in response to a stimulus during use.

17. The ventricular repair system of claim 16, further comprising an energy source configurable to provide the stimulus, and wherein the energy source is rechargeable.

18. The ventricular repair system of claim 16, further comprising a controller in communication with the patch during use, wherein the controller is configurable to substantially regulate the stimulus during use.

19. The ventricular repair system of claim 18, wherein the controller is programmable.

20. The ventricular repair system of claim 1, wherein the patch further comprises an ion exchange material.

21. The ventricular repair system of claim 1, wherein the patch further comprises a shape memory metal.

22. The ventricular repair system of claim 1, wherein the patch further comprises a noble metal.

23. The ventricular repair system of claim 1, wherein the patch further comprises an electrosensitive gel.

24. The ventricular repair system of claim 1, wherein the patch further comprises biological material.

25. The ventricular repair system of claim 1, wherein the patch further comprises autologous cells.

26. The ventricular repair system of claim 1, wherein the patch further comprises xeno transplanted materials.

27. The ventricular repair system of claim 1, wherein the patch further comprises skeletal muscle cells.

28. The ventricular repair system of claim 1, wherein the patch further comprises bone marrow cells.

29. The ventricular repair system of claim 1, wherein the patch further comprises cardiac muscle cells.

30. The ventricular repair system of claim 1, wherein the patch further comprises smooth muscle cells.

31. The ventricular repair system of claim 1, wherein the patch further comprises a growth factor.

32. The ventricular repair system of claim 1, wherein the patch further comprises bioabsorbable material.

33. A ventricular repair system, comprising:

a patch comprising a predetermined shape, wherein the predetermined shape is substantially conical and further comprises a tip, wherein the patch is configurable to alter at least a portion of a contour of a ventricle to a second contour of the ventricle substantially similar to the predetermined shape during use, and wherein the tip is configured to assist in defining an apex of a repaired ventricle.

34. A method for reconstructing a ventricle of a human heart, comprising:
opening the ventricle;
positioning a patch in the ventricle, wherein the patch is substantially nonplanar;
sizing the patch;
coupling at least a portion of the patch to at least a portion of the ventricle; and
excluding at least a portion of non viable tissue.

35. The method of claim 34, wherein the ventricle comprises a left ventricle of a human heart.

36. The method of claim 34, wherein sizing the patch comprises sizing the patch relative to non viable tissue.

37. The method of claim 34, wherein sizing the patch comprises sizing the patch relative to an opening.

38. The method of claim 34, wherein sizing the patch comprises:
indicating a position of non viable tissue on the patch;
removing the patch from the ventricle; and
removing excess material from the patch.

39. The method of claim 34, wherein sizing the patch comprises:
indicating a position of non viable tissue on the patch; and
removing excess material from the patch.

40. The method of claim 34, further comprising reforming a contour of at least a portion of the ventricle comprising:
positioning a shaping device in the ventricle;
positioning at least one suture in the ventricle along at least a portion of a line intersecting the shaping device and non viable tissue; and
securing at least a portion of the ventricle around at least a portion of the shaping device.

41. A method for reconstructing a ventricle, comprising:
opening the ventricle;
positioning a patch in the ventricle;
reforming a contour of at least a portion of the ventricle around the patch such that an apex is formed in the ventricle;
coupling at least a portion of the patch to at least a portion of the ventricle; and
excluding at least a portion of non viable tissue.

42. The method of claim 41, wherein the ventricle comprises a left ventricle of a human heart.

43. The method of claim 41, further comprising:

positioning at least one suture in the ventricle along at least a portion of a line intersecting akinetic tissue and viable tissue;

positioning a shaping device in the ventricle; and

wherein at least one of the sutures is configured to reform the contour of at least a portion of the ventricle around the shaping device.

44. The method of claim 43, wherein at least one of the sutures is a Fontan stitch.

45. The method of claim 43, wherein at least a portion of the shaping device extends beyond at least one of the sutures.

46. The method of claim 45, further comprising:

sizing the patch such that the shape of the patch is substantially similar to at least a portion of the shaping device extending beyond at least one of the sutures;

coupling the patch to at least a portion of the ventricle; and

removing the shaping device.

47. The method of claim 45, wherein the patch is coupled to a at least a portion of the ventricle hemostatically.

48. A ventricular repair system, comprising:

a patch comprising a predetermined shape, wherein the predetermined shape is substantially nonplanar.

49. A method for reconstructing a ventricle, comprising:

positioning a patch in the ventricle; and

coupling at least a portion of the patch to at least a portion of the ventricle.

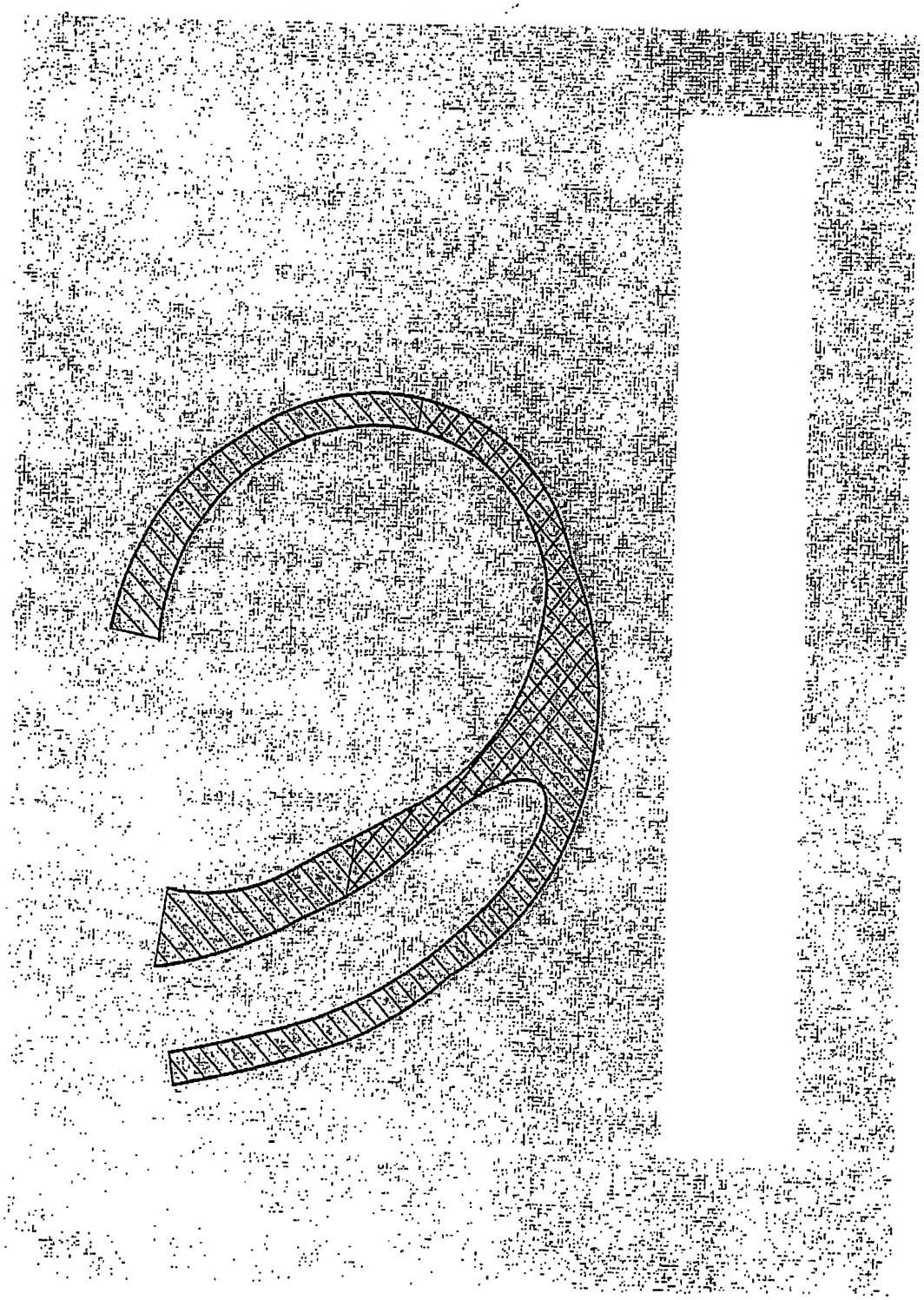


Fig. 1

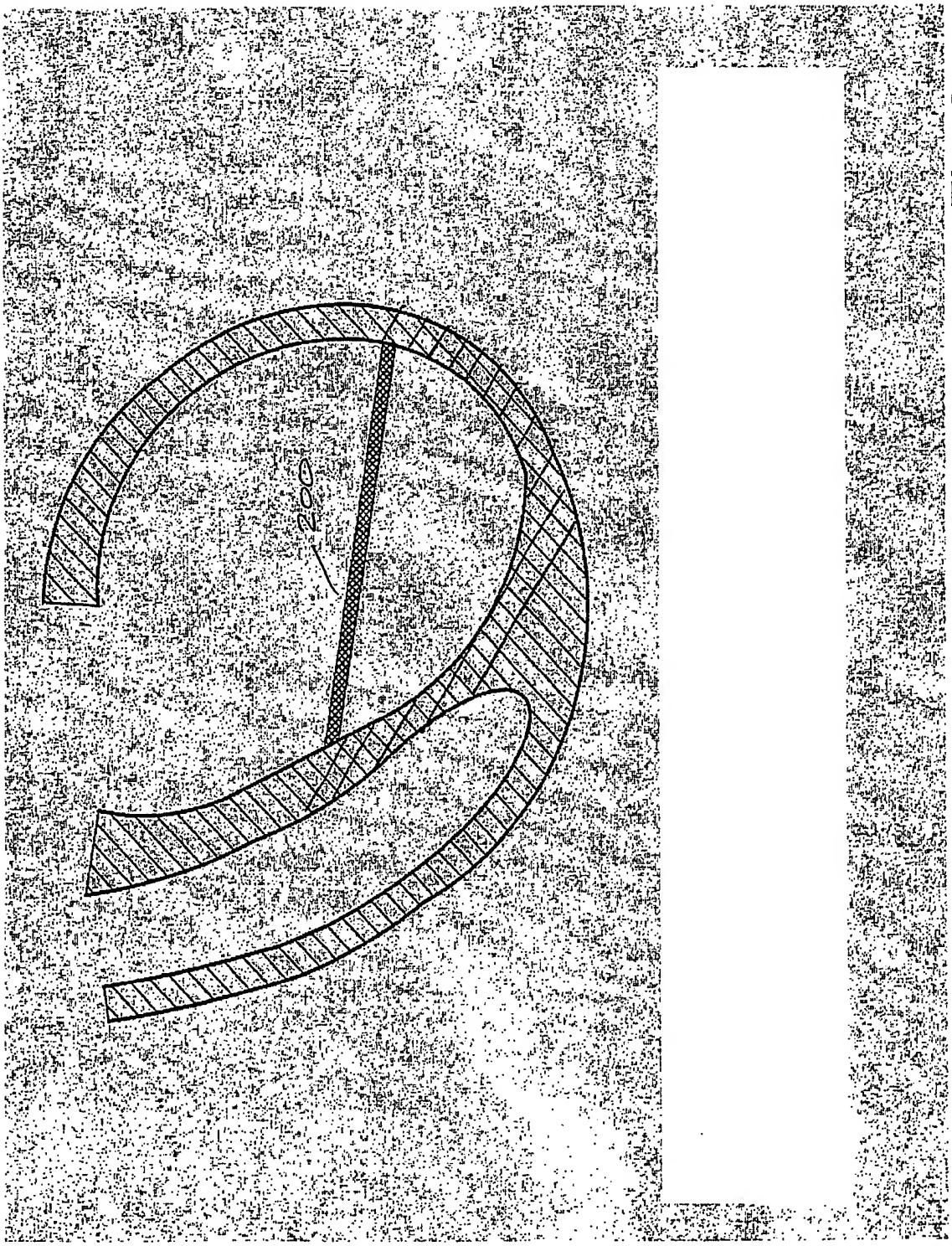
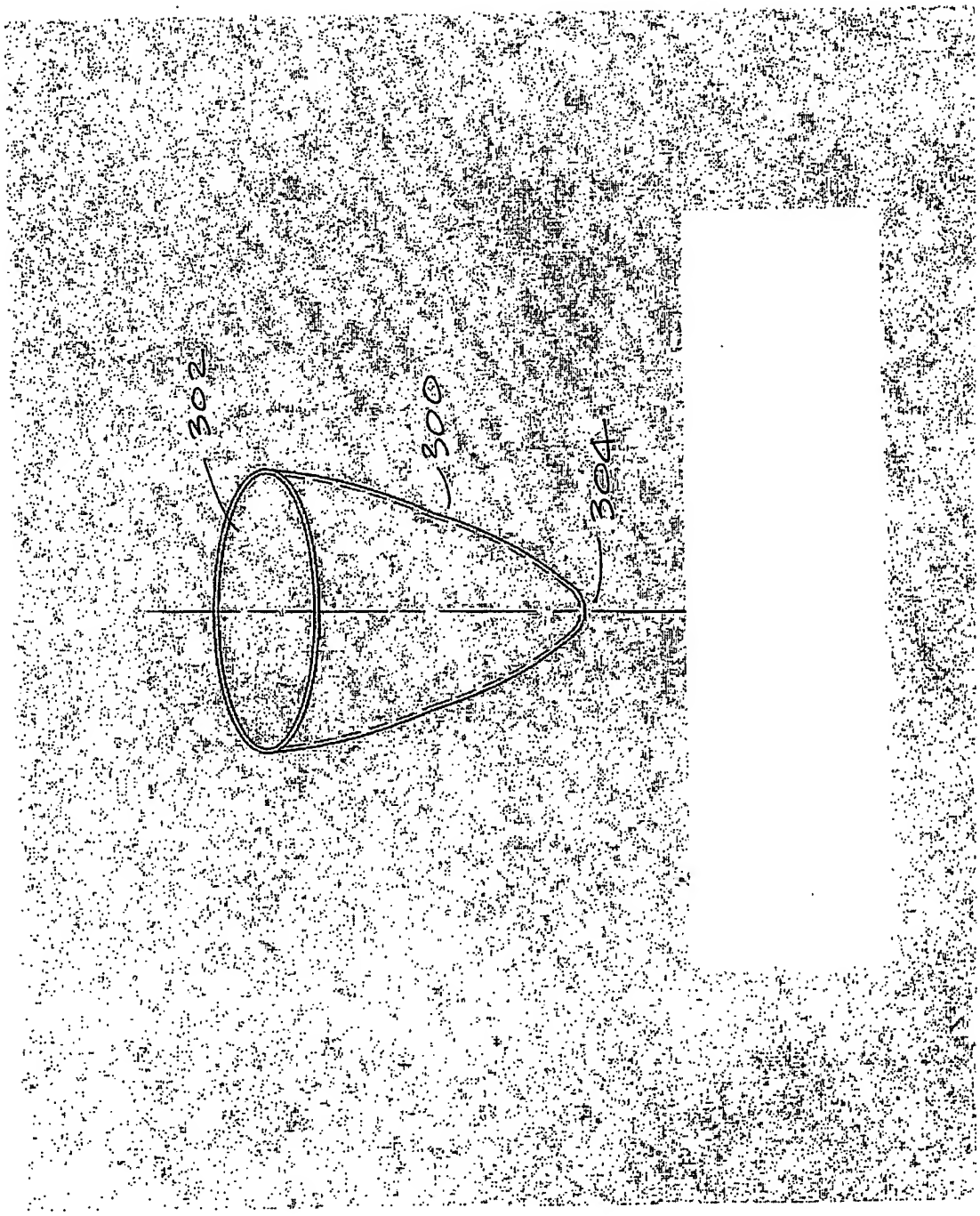


Fig. 2

Fig. 3



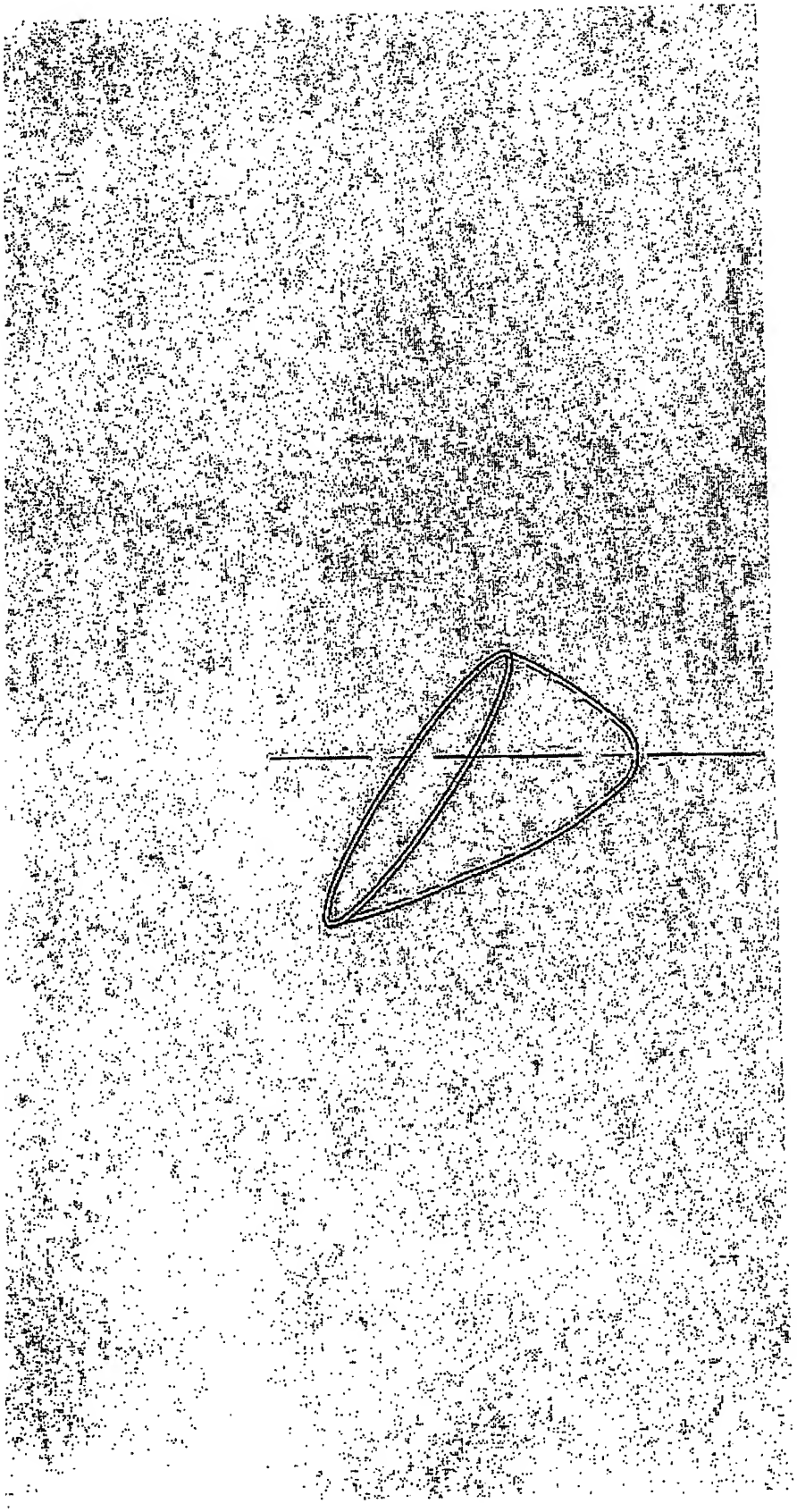


Fig. 4

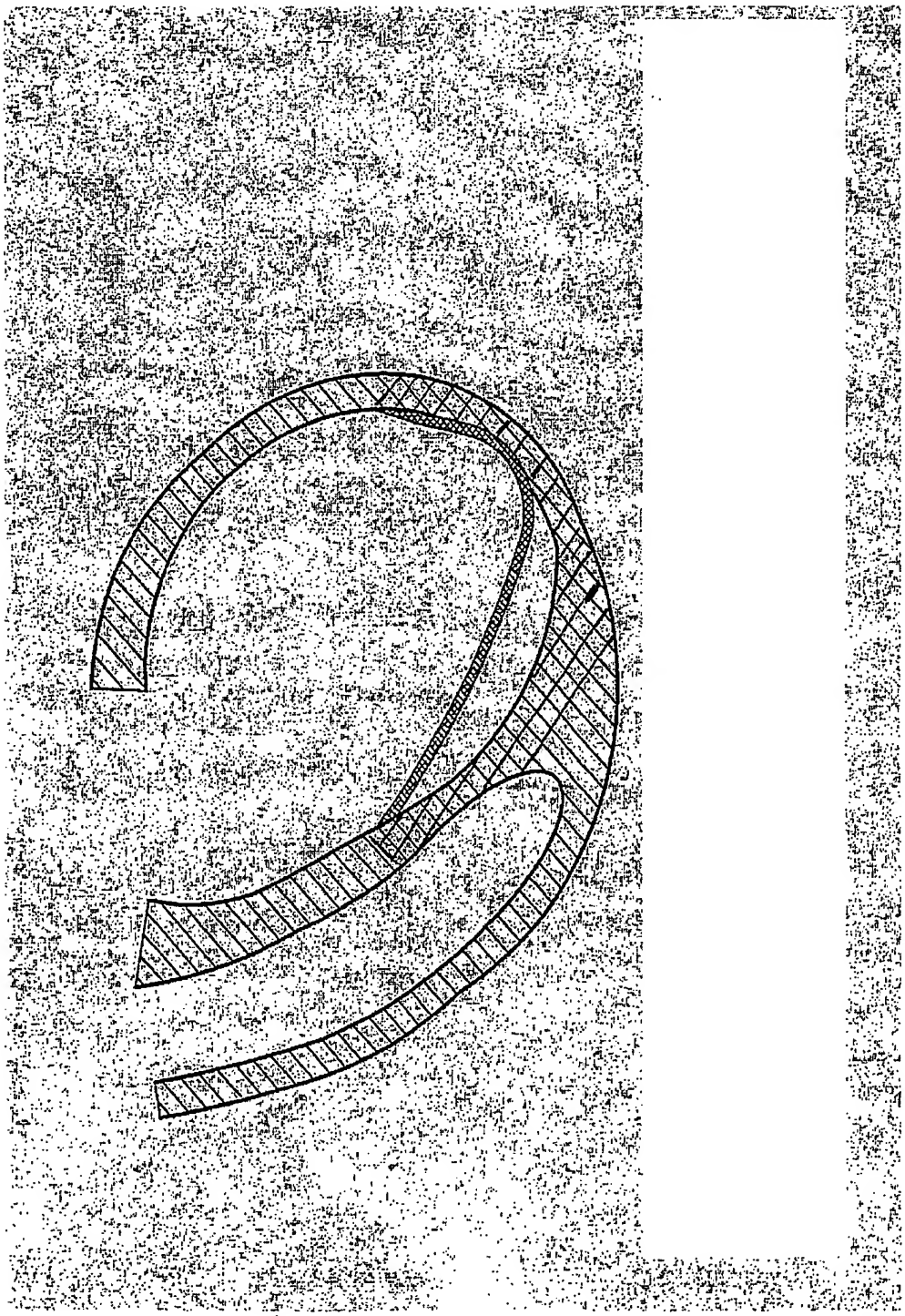


Fig. 5